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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,326	04/03/2006	Yusuke Nakamura	082368-003000US	9667

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EXAMINER	
GUSSOW, ANNE	

ART UNIT	PAPER NUMBER
1643	

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01/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,326	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Anne M. Gussow	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7,17-25,28,29,31,36,43-45,49 and 77* is/are pending in the application.

4a) Of the above claim(s) *5,17-25,28,29,31,43-45 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,7,36 and 77* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/ are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 14, 2007 has been entered.

2. Claims 1, 28, 31, 36, 43, and 49 have been amended.

Claim 77 has been added.

Claims 6, 8-16, 26, 27, 30, 32-35, 37-42, 46-48, and 50-76 have been cancelled.

Claims 5, 17-25, 28, 29, 31, 43-45, and 49 remain withdrawn.

3. Claims 1, 3, 4, 7, 36, and 77 are under examination.

4. The following Office Action contains NEW GROUNDS of Rejection.

Rejections Withdrawn

5. The rejection of claims 1, 3, 4, and 7 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting the phrase "cell proliferative activity" is withdrawn in view of applicant's amendment to the claims.

6. The rejection of claim 36 under 35 U.S.C. 112, second paragraph, as being indefinite for not reciting a binding limitation is withdrawn in view of applicant's amendment to the claims.

Rejections Maintained/ NEW GROUNDS of Rejection

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The rejection of claims 1, 3, 4, and 7 and newly added claim 77 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained.

The response filed October 30, 2007 has been carefully considered but is deemed not to be persuasive. The response states that the USPTO itself has deemed a single disclosed species to be representative of the claimed genus of hybridizing homologs and sequence variants encompassed by the instant claims. Specifically, the high degree of sequence identity and/or the highly stringent hybridizing techniques required by the claims, coupled with the specified restriction on function, results in a genus of structurally similar nucleotides (see response pages 13-14).

The response also states that Applicants have indeed provided guidance as to structural domains associated with functional activity, noting that the predicted NFXL1 protein contains a ring finger domain (codons 160-219), 12 NFX type Zn-finger domains (codons 265-794), a coiled coil region (codons 822-873), and a transmembrane region (codons 889-906) and is further known to bind to MGC10334 and/or CENPC1. See, page 8, lines 18-27 and Figure 9b. Following this guidance, one skilled in the art would expect those regions outside the designated domains to be most tolerant of variation (see response page 14).

In response to this argument, regarding hybridizing homologs, while the guidelines disclose that a single species is sufficient to enable a genus with limited variability, the instant genus would contain a fair amount of variability because molecules which hybridize do not specifically bind to each and every residue of a sequence, therefore the structure of the hybridizing molecule would have significant variation. When given the broadest reasonable interpretation, the claims read on fragments encoded by partial complements to a polynucleotide that hybridizes to a complement of SEQ ID No. 11.

Regarding the structural and functional activity, applicant has identified a number of common domains located in the NFXL1 protein, however, applicant has not identified which of these domains are required for the claimed functional activity of promoting cell proliferation or binding to MGC10334 and CENPC1. It is conceivable that the functional region of the NFXL1 protein lies outside of one of the identified domains, thus mutation of residues outside of these domains would affect the structure and function of the

protein. Example 14 of the training guidelines, as cited by applicant, refers to a specific detailed structure having a specific detailed function as an enzyme.

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

9. The rejection of claims 1, 3, 4, 7, and newly added claim 77 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.

The response filed October 30, 2007 has been carefully considered but is deemed not to be persuasive. The response states that possession of a genus may be satisfied through sufficient description of a "representative number of species" by: (a) an actual reduction to practice, (b) a reduction to drawings, or (c) disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics sufficient to show the applicant was in possession of the claimed genus. In other words, possession of a genus can be evidenced by describing the distinguishing identifying characteristics common to the divergent species encompassed. See, M.P.E.P. § 2163.02.
In this context, a "representative number of species" means that the species which are actually described are representative of the entire genus. Thus, when there is substantial variation with the genus, one must describe a sufficient variety of species to reflect the variation. What constitutes a representative number is an inverse function of

the skill and knowledge in the art. Satisfactory disclosure of a representative number of species depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed.

In response to this argument, the claimed genus would have sufficient variety because applicant has not identified the specific regions of the protein required to provide the functional activity of binding to MGC10334 and CENPC1 or promoting cell proliferation. Applicant has identified common domains in the protein to be a ring finger domain, Zn-finger domains, a coiled coil region, and a transmembrane region but has not provided evidence that any of the identified domains are involved in the claimed functional activity of the protein.

Therefore, after a fresh consideration of the claims and the evidence provided, the rejection is maintained.

10. Claims 1, 3, 4, 7, 36, and 77 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1(c) is drawn to a CGX2 polypeptide encoded by a polynucleotide that hybridizes to a complement of the nucleotide sequence of SEQ ID No. 11. While the CGX2 polypeptide of SEQ ID No. 12 is adequately described in the specification as

filed, thereby providing an adequate basis for the polypeptide of SEQ ID No. 12 and the complete complement of the nucleic acid sequence of SEQ ID No. 11, there is insufficient written description as to the identity of fragments of polypeptides encoded by partial complements to a polynucleotide that hybridize to a complement of SEQ ID No. 11 that would still maintain the function of the polypeptide.

The specification as filed does not provide adequate written description support for a polypeptide encoded by a polynucleotide that hybridizes to a complement of the nucleotide of SEQ ID No. 11. Polypeptides having diverse functions are encompassed by the phrase hybridizes to a complement. Thus a broad genus having potentially highly diverse functions is encompassed by the phrase hybridizes to a complement and conception cannot be achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention. The sequence itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

Therefore, only the full length polypeptide of CGX2 meets the written description provision of 35 U.S.C. 112, first paragraph. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed. (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. (See Vas-Cath at

page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, & 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Anne M. Gussow

December 27, 2007

/Larry R. Helms/
Supervisory Patent Examiner